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SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/071,052	06/04/93	KREAMER	J 467312465

EXAMINER
CRIARES, T

12M2/0910

DAVIS, HOCKENBER, WINE,
BROWN, KOEHN & SHORS
666 WALNUT ST., STE. 2500
DES MOINES, IA 50309

ART UNIT	PAPER NUMBER
1205	2

DATE MAILED: 9/10/93

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☑ This application has been examined ☐ Responsive to communication filed on _____ ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), ____ days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☑ Notice of References Cited by Examiner, PTO-892.
2. ☐ Notice re Patent Drawing, PTO-948.
3. ☐ Notice of Art Cited by Applicant, PTO-1449.
4. ☐ Notice of informal Patent Application, Form PTO-152.
5. ☐ Information on How to Effect Drawing Changes, PTO-1474.
6. ☐ _____

Part II SUMMARY OF ACTION

1. ☑ Claims 1-10 are pending in the application.
   Of the above, claims _____ are withdrawn from consideration.
2. ☐ Claims _____ have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☑ Claims 1-10 are rejected.
5. ☐ Claims _____ are objected to.
6. ☐ Claims _____ are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable. ☐ not acceptable (see explanation or Notice re Patent Drawing, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____ has (have) been ☐ approved by the examiner. ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed on _____, has been ☐ approved. ☐ disapproved (see explanation).
12. ☐ Acknowledgment is made of the claim for priority under U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____; filed on _____.
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

EXAMINER'S ACTION

PTOL-326 (Rev. 9-89)

Claims 1-10 are presented for examination.

Claim 1 is drawn to a composition of aspirin and a Vitamin.

Claims 2-4 are drawn to treating vascular disease in humans using a composition of aspirin and a vitamin.

Claim 5 is drawn to a composition of aspirin and at least two vitamins.

Claim 6 is drawn to a method of treating vascular disease in humans using aspirin and at least two vitamins.

Claim 7 is drawn to a composition of aspirin and a trace element.

Claims 8 and 10 are dependent on claims 1 and 2 respectively and claim 9 is drawn to a method of treating vascular disease in humans using aspirin and a trace element.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as the proportions of active agents present in the synergistic compositions are not clearly set forth in the specification. The dose ranges on page 13 do not set forth what ratios of active agents will yield the desired synergistic effect.

Claims 1-10 are rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the objection to the specification.

Claims 1-10 are rejected under 35 U.S.C. § 112, first paragraph, as the disclosure is enabling only for claims limited to the compositions which yield the synergistic effect. See M.P.E.P. §§ 706.03(n) and 706.03(z).

The claims neither recite the ratios of active agents which will yield the desired results nor the vascular disorder to be treated.

More specifically the phrases "preventing and treating" (claims 2-4 and 9) "amelioration" (claims 1, 5-8 and 10) and "vascular disease" (claims 1 et seq) are deemed beyond applicants' limited specification. The applicants specification demonstrates only a limited combination may have a synergistic activity to treat atherosclerosis.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that

> the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 1-10 are rejected under 35 U.S.C. § 102(b) as being anticipated by applicant's admissions.

The applicant has admitted throughout the specification that the individual active agents claimed therein are known to have the activity claimed. For example see page 1, where it is stated that aspirin, vitamins and trace elements individually are known to treat atherosclerosis. The use of any of these known claimed active agents to treat atherosclerosis anticipates the claimed invention. The method and composition would be inherent. See Ex parte Novitski 26 USPQ2d 1389.

Claims 1-10 are rejected under 35 U.S.C. § 103 as being unpatentable over the applicants' admissions at page 1. The applicants admit that each of the generically claimed active agents have been used to treat atherosclerosis.

Claims 1-10 are rejected under 35 U.S.C. § 103 as being unpatentable over Igarashi et al (778), Fratzer (603) and Frisbee (081). Igarashi and Fratzer each teach n their abstracts the use of Vitamin E to treat a vascular disease and Frisbee discloses at

column 1, lines 25 to 30 that aspirin can be used to treat vascular diseases.

It is deemed well settled patent law that the combination of ingredients of known character where the results obtained are no more than additive of the individual character will not be patentable. It is clear from applicants admissions that each of the claim designated ingredients are known to have beneficial results in patients. The use of the two ingredients or three in a single combination would have been obvious to those skilled in the art given the known characteristics of each component.

The data has been carefully reviewed but is no deemed persuasive. There is no clear showing of the synergistic activity of the claimed composition and pharmaceutical effect. The tables do not set forth the amounts of active agents used in each instance.

For these reasons the claimed subject matter is deemed to fail to patentably distinguish over the state of the art as represented by the cited references. The claims are therefore properly rejected under 35 U.S.C. 103.

None of the claims are allowed.

The references cited in PTO-892 but not discussed are cited to show the general state of the art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Criares whose telephone number is (703) 308-4607.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.

T.J. Criares
Examiner
Art Unit 1205
September 9, 1993